

REMARKS

I. Status of Claims

By this amendment, Applicant respectfully proposes to amend claim 9, to recite (relative to claim 9 as presented on March 10, 2005) "A method of treating to decrease a [risk of] mortality rate...", consistent with the statements in the Office Action at page 6 and the November 27, 2007, telephone conference with Examiner Spivak, discussed further below. Support for this amendment can be found, for example, in the issued patent at column 1, lines 9-14 ("The present invention relates to a new method of treatment ... for decreasing the mortality of patients suffering from congestive heart failure"); column 3, lines 59-63 ("carvedilol [is] able to decrease the mortality resulting from CHF in humans by about 67 percent."); and column 6, lines 61-62 ("This represented a reduction in risk of death by [carvedilol] of 67%").

Without prejudice or disclaimer, this amendment also proposes the cancellation of claims 1-6, 12-15, 17, 18, 22, 23, and 26-30. These claims had been rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking written description support, as stated in the Office Action and further to the November 27, 2007, telephone conference with Examiner Spivak. Of these claims, claims 1-6 were original claims issued in U.S. Patent No. 5,902,821, while claims 12-15, 17, 18, 22, 23, and 26-30 were added in the November 23, 2003, Preliminary Amendment.

Further to the requirement on page 2 of the Office Action that

a clean copy of all new claims (those not issued in the patent) - with underlining - is required to show that these have been added relative to the issued patent[.]

all of the non-canceled claims added relative to the issued patent are included in the listing of claims in underlined format.

No new matter has been added.

A supplemental reissue declaration will be forthcoming.

II. Interview Summary

Applicant thanks Examiner Spivak for her time and courtesy in conducting a telephonic interview with their undersigned representative on November 27, 2007. A summary of the subject matter addressed is as follows.

1. The Examiner confirmed that, with the exception of claims 12 and 13, the claims listed as objected to on page 1 of the Office Action appear to be objected to solely for reasons related to appropriate format for reissue claim amendments, as noted on page 2 of the Office Action.

2. The Examiner confirmed that claims 12 and 13, while listed on page 1 of the Office Action as objected, should have been listed as rejected, consistent with the bases for the rejections under 35 U.S.C. § 112, first paragraph, discussed at the top of page 3 of the Office Action.

3. The Examiner indicated that, consistent with the comment in bold on page 6 of the Office Action, the Examiner would favorably consider an after final amendment changing the preamble of claim 9 from "A method of treating to decrease a risk of mortality" to --A method of treating to decrease a [risk] mortality rate,-- though the Examiner did not take a final position on whether or not this amendment would overcome the rejection of Claim 9 under 35 U.S.C. § 102.

III. Rejection under 35 U.S.C. §112, first paragraph

Without conceding the rejection, the rejection of claims 1-6, 12-15, 17, 18, 22, 23, and 26-30 under 35 USC § 112, first paragraph, for an alleged lack of written description (Office Action, pg. 4*) is moot in view of Applicant's proposed amendments herein.

Applicant notes that it is preserving the right to pursue the subject matter in a continuation application.

IV. Rejection under 35 U.S.C. § 102

Claim 9 was rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Metra (Metra et al., Journal of the American College of Cardiology 24(7), pg. 1678-87 (Dec. 1994)). (Office Action, pg. 5.) Applicant respectfully disagrees and traverses the rejection for the reasons of record, including pursuant to (1) the remarks at pages 10-20 of its August 13, 2007, Response and (2) the Affidavit of Dr. Lukas, submitted as an exhibit to its April 2, 2007, Response, both of which are incorporated herein. For example, as explained further therein, Metra is directed, at most, to the treatment of quality of life considerations. It does not teach or suggest treatment to reduce a risk of death or mortality rate.

Consistent with this distinction and the Examiner's comments at page 6 of the Office Action addressed to mortality "rate," Applicant respectfully submits that the amendment of claim 9 proposed herein further renders moot the rejection.

* As noted in section II above, the rejection of claims 12 and 13 under this ground was confirmed by in the November 27, 2007, telephonic interview.

Conclusion

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 7-10, 16, 19-21, 24 and 25 in condition for allowance. Applicant submits that the proposed amendment of claim 9 does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Further, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

The Examiner is respectfully invited to contact Applicant's undersigned representative by telephone at (202) 408-4092 to address any additional matters pertaining to this application.

Respectfully submitted,

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